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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,198	10/26/2001	Peter M. Lloyd	509032001600	1707

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EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3761	14

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,198	LLOYD ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3761	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *48-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47 and 80-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6, 10*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-47 and 80-83 to method steps in Paper No. 13 is acknowledged. The traversal is on the ground(s) that method and apparatus claims are under the same calls and subclass. This is not found persuasive because the process for using the product as claimed can be practiced with another materially different product. Examples of some classes where the method could be classified would be class 122, 261, and 423.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 48-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected product, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claim Objections

3. Claim 71 is objected to because of the following informalities: the preamble of claim 71 is to an apparatus/device, however the body of the claim includes method steps. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10, 18, and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 10, 18, and 31 the word "means" is preceded by the word(s) "mechanical" or "inductive" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7, 9, 12-15, 17, 19-22, 24-28, 30, 32, 35, 36, 39-44, 46, 47, 80, and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerth et al. 4735217.

9. Gerth teaches a method for delivering a physiologically active compound to a patient comprising the steps of: heating the physiologically active compound to a temperature and for a duration that results in an acceptably low level of decomposition; simultaneously passing a gas across the surface of the compound to achieve a desired rate of vaporization; and administering the resulting aerosol to a patient; where the gas is air at ambient temperature; wherein air is passed across the surface at a rapid rate;

wherein the rapid rate does not result in a large rise in the air temperature and does not result in the compound being blown downstream with the air without being first vaporized; wherein the vaporized compound is rapidly mixed into the air to cool and preclude additional decomposition of the compound; wherein the rapid rate of air passing across the surface is caused by inhalation through the device by the patient (col. 6, lines 33-50); wherein the said compound is menthol and nicotine (col. 8, lines 43-47); wherein the compound is contained in a heating vaporization-mixing zone having a sufficiently restricted cross-sectional area to increase the rate of air passing across the compound and to achieve the desired rate of vaporization; wherein the mixing zone is designed to rapidly cool the vaporized compound (col. 6, lines 42-46); wherein the compound is heated with resistive heaters (col. 5, line 68); wherein the compound is deposited onto a substrate 40 having a surface area up to one meter square; wherein the substrate is porous and allows for the passing of the gas through the substrate (col. 8, lines 51-55); feeding the substrate into a heating-vaporization-mixing zone; wherein the substrate is constructed and positioned in the gas stream so that the compound is vaporized into a small volume of gas; wherein the gas is passed across a portion of the/entire surface of the substrate; administering the resulting aerosol to an organ or tissue of a patient; and wherein the aerosol is administered to the mucosa.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 16, 17, 29, 31, 37, 38, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al.

12. Gerth et al. discloses wherein the compound is heated with resistive heaters. Gerth does not disclose expressively wherein the compound is heated with photon energy or by inductive means.

At the time the invention was made, it would have been an obvious matter to a person of ordinary skill in the art to use photon or inductive means for heating because the Applicant has not disclosed that photon or inductive means for heating provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with resistive heaters because the heaters are mechanical expedients of each other.

Therefore, it would have been an obvious to modify Gerth et al. to obtain the invention as specified in claims 16, 17, 29, 31, and 45.

13. As to claims 37 and 38, Gerth et al. discloses the claimed invention except for wherein the compound is heated to the point of vaporization between 1 and 10 milliseconds or 10 and about 100 milliseconds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to heat the compound for the specified amount of time, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

14. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al. in view of von Sarela 5605146.

15. Gerth et al. teaches the method as applied to the above rejections. Gerth fails to teach wherein the air passing across the surface is generated by mechanical means.

Sarela teaches a method of inhalation that uses a common mechanical means. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the method of using a mechanical means to aid or force circulation of air for breathing/moving vapor (col. 3, lines 29-30).

16. Gerth/Sarela teaches the method 7 wherein the resulting mixture of the vaporized compound and air is further mixed into an additional air stream to further cool and preclude additional decomposition of the compound (mixture + air stream provided by the mechanical means/fan).

17. Claim 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al. in view of Howell et al. 5743251.

18. Gerth et al. teaches the method of claim 1. Gerth et al. fails to specifically teach wherein the compound is heated so that the said compound vaporizes at the lowest possible temperature.

Howell et al. teaches a method of heating with a common low temperature. Therefore it would have been obvious to one having ordinary skill in the art at the time

the invention was made to include the method of heating to a low temperature to prevent the compound being heated from becoming unstable (col. 3, lines 11-19).

19. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al. in view of Sprinkel et al. 5649554.

20. Gerth et al. teaches the method of claim 22. Gerth et al. fails to teach wherein the rapid rate does not result in a pressure drop across the restricted cross-sectional area of greater than about 10 inches of water.

Sprinkel et al. teaches a method wherein the pressure drop is no greater than about 10 inches of water. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the pressure drop of no greater than about 10 inches of water to simulate the resistance to air flow produced by smoking a cigarette (col. 5, lines 63-67; col. 6, lines 1-7).

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al. in view of Vinegar et al. 6632047.

22. Gerth et al. teaches the method of claim 31. Gerth et al. fails to teach wherein the foil substrate is stainless steal.

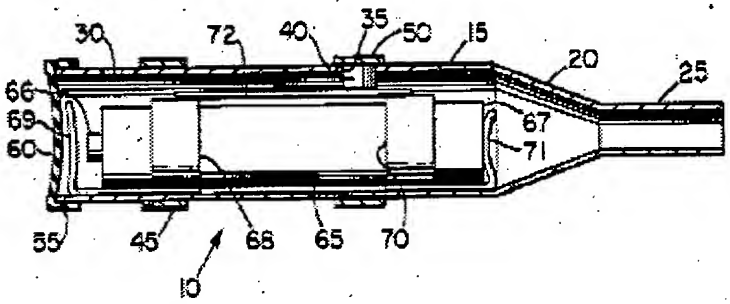
Vinegar et al. teaches a common stainless steal substrate for heating. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to make use of stainless steal because of its known scientific properties and cost effectiveness (col. 7, lines 15-21).

23. Claims 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerth et al. in view of Shanbrom 3949743.

24. Gerth et al. teaches the method of claim 80. Gerth et al. fails to teach wherein the aerosol is administered to the eye or to the skin.

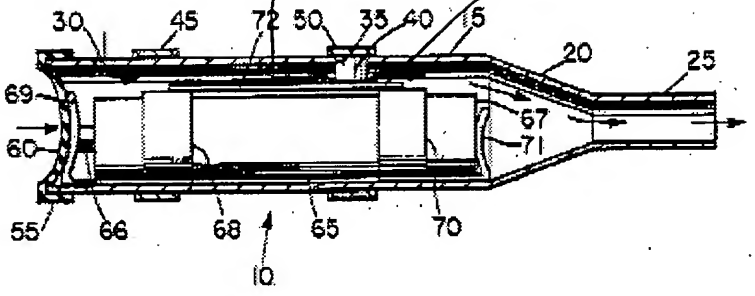
Shanbrom teaches a method wherein an aerosol is administered to the eye or the skin for treatment of disorders. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the method of administering aerosol to the eye or to the skin for treatment of disorders (col. 3, lines 16-19).

Fig. 4



restricted cross-section

Fig. 5 fail



Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM
November 26, 2003

WEILUN LO
SUPERVISORY PATENT EXAMINER
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